

PATENT SPECIFICATION 692,578



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COMPLETE SPECIFICATION

Improvements in or relating to Drape Sheets for Surgical Use

We, MINNESOTA MINING AND MANUFACTURING COMPANY, a corporation organised under the laws of the State of Delaware, United States of America, of 900, 5 Fauquier Avenue, City of St. Paul, State of Minnesota, United States of America, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which 10 it is to be performed, to be particularly described in and by the following statement:—

This invention relates to a sterile-packaged adhesive-coated drape sheet especially adapted for utilization in surgical operations, for dressing wounds, and for 15 kindred uses.

The present invention provides a 20 sterilized by comprising: (1) a surgically-sterile adhesive-coated surgical drape sheet formed of a synthetic plastic film sheet which is soft and pliable so as to be readily draped over the contours of the 25 human body, a normally tacky pressure-sensitive adhesive bonded to a relatively small portion of said film so as to provide a skin-adhering area adjacent to a surgical operative site when the drape 30 sheet is applied to a body, the major portion of the drape sheet being adapted to cover a relatively large adjoining skin area without adhering thereto, the film and the adhesive being waterproof and 35 resistant to body fluids and being substantially non-toxic to the human skin; (2) a backing sheet or liner temporarily covering the tacky adhesive area and being removable therefrom without causing offsetting of the adhesive from the film 40 sheet; (3) a sealed package enclosing said drape sheet and adapted to maintain the latter in a surgically sterile condition, the composite sealed package containing the 45 surgical drape sheet having been sterilized as a unit so as to insure a surgically-sterile condition of the drape sheet therein, said drape sheet being unharmed

by said sterilization and being ready for removal and immediate use by a surgeon whenever desired, without further sterilization being required.

It is essential in surgery that the skin area of the patient adjacent the incision be as nearly sterile as possible and like 55 considerations apply in the case of wound dressings. We have found that this condition may be more easily maintained by making use of a sterile-packaged drape sheet comprising a thin, soft, pliable, 60 water-resistant body or film that can be made to adhere to the skin over, around or in the vicinity of the wound or the area where the operation is performed. Accordingly, our drape sheet is provided 65 on at least part of one side with a pressure-sensitive adhesive capable of adhering firmly both to the film and to the patient's skin. The adhesive film and any other elements making up the drape 70 sheet, together with the package containing them, are sterilized as a unit and kept sterile until the drape sheet is to be used.

After the desired body surface area of 75 the patient has been suitably prepared, the sterile package so made up is opened and application of our drape sheet is made. For surgical uses, such sheet may and usually will have a preformed opening 80 therein, but, if desired, it may be left intact so that a surgical incision may be made directly therethrough, the operation being carried out in either case in much the usual manner. For use as a 85 wound dressing, the sheet will usually be left intact, but, if desired, may be provided with a preformed opening or incised as necessary. Even relatively long incisions or wounds may effectively be 90 closed without stitches or sutures and without clips by applying one or more adhesive-coated tapes to the drape sheet across the incision or wound in order to hold the same closed during healing. The 95 drape sheet adheres firmly to the skin

and, being water-resistant, is not affected to any great extent by body fluids.

By use of our sterile-packaged drape sheet in these and like ways, chances of infection are reduced, scars minimized, and desirable healing conditions maintained.

It is among the objects of our invention to provide a sterile-packaged drape sheet that is particularly adaptable for surgical and like uses. Other objects include the provision of a sterile surgical covering lending itself to necessary handling without needless contamination of the covering; the provision of a sterile adhesive-coated film with an associated supporting base or backing sheet for the adhesive which film is susceptible of long storage life without deterioration, of being easily cut to a desired shape, and of being readily separated from the supporting base or backing sheet prior to use, and the provision of a folded adhesive-coated pellicle which, together with the package containing it, may be subjected as a unit to sterilizing temperatures without developing undue softening, oozing, sticking or undesired changes in the physical properties of any component elements of the unit. Other objects of the invention will appear from the detailed description which follows of certain of the preferred embodiments thereof.

For an understanding of our invention, reference may be had to the accompanying drawings, in which:

Figure 1 is an isometric view showing the drape sheet of the invention as it appears after having been folded, sealed in an inner wrapper, sterilized, and enclosed in an outer wrapper;

Figure 2 is an isometric view of the sealed inner wrapper containing the drape sheet as it appears after removal of the outer wrapper;

Figure 3 is an isometric view of a partly unfolded drape sheet after its removal from the inner wrapper, such view showing the drape sheet as square in shape and provided with a round preformed opening surrounded by an annular backing sheet of the nature of a liner;

Figure 4 is an isometric view showing another form of drape sheet provided with a preformed oval opening in which, as in Figure 3, such opening is surrounded in the immediate vicinity thereof by an adhesive protected by a backing sheet of the nature of a liner;

Figure 5 is a section, on an enlarged scale, on line 5-5 of Figure 4;

Figure 6 is a similar section showing the tab pulled up from its normal position on the drape sheet;

Figure 7 is a similar section showing the tab and a considerable part of the backing sheet pulled away from the drape sheet, in part exposing the adhesive;

Figure 8 is a fragmentary isometric view similar to Figure 5 showing the drape sheet after the backing sheet has been completely pulled away from it;

Figure 9 is an isometric view showing still another form of drape sheet, the same being carried by a relatively stiff supporting base of the nature of a liner from which part of the drape sheet is shown as having been peeled back;

Figure 10 is an enlarged fragmentary isometric view looking in the direction indicated by arrows 10-10 of Figure 9, 85 and

Figure 11 is an enlarged fragmentary isometric view similar to that of Figure 10 but reversed to show the details of the bottom of the supporting base.

As indicated in Figures 1 to 3, in addition to the drape sheet itself, the sterile-packaged drape sheet of the invention preferably makes use of an inner wrapper in which the drape sheet is inserted, sealed and sterilized, and, of somewhat larger dimensions than the dimensions of the inner wrapper, an outer wrapper in which the inner wrapper, with drape sheet enclosed, is inserted and within which it is sealed to protect the inner wrapper and the enclosed drape sheet against contamination. If, as may but need not necessarily be the case, the drape sheet includes a supporting base or backing sheet that is substantially co-extensive with an associated layer of pressure-sensitive adhesive, the form or nature thereof may be revealed in relief or be visible through the material comprising the inner wrapper; similarly, notwithstanding the presence on the surface of the outer wrapper of printing to show a trade mark or, for example, instructions for use, the form of the inner wrapper may and usually will be apparent through the outer wrapper. These conditions are illustrated in Figures 1 and 2.

In Figure 1, A designates the outer wrapper, the same having an integral end flap B forming part thereof which has been folded over onto the body portion of the outer wrapper A and sealed in position by a strip of transparent tape C provided on its inner face with an application of a water-resistant or waterproof heat-sealing adhesive of one of the types known in the packaging art. Appearing through the material comprising outer

wrapper A, which conveniently may be of Cellophane (Registered Trade Mark), glassine, wax-coated paper or some similar transparent or translucent material, is inner wrapper D. The latter, shown to better advantage in Figure 2, is similar to outer wrapper A in that it includes an end flap which has been folded over onto the body portion of the wrapper and sealed in position by a strip of transparent tape carrying a like heat-sealing adhesive. Within the confines of inner wrapper D is the drape sheet E, the same being represented as having been folded. Figure 3 shows drape sheet E as partially opened out following its removal from inner wrapper D, a single fold remaining to be opened out being indicated in dotted lines as underlying the main portion of the drape sheet.

In the form shown in Figure 3, drape sheet E, which is square in shape, includes a round central opening immediately surrounded by an annular backing sheet overlying a ring of pressure-sensitive adhesive; however, these details, in and of themselves, are not necessarily features of the invention insofar as it relates broadly to sterile-packaged drape sheets.

In practice, the drape sheet, if of a size requiring folding, is folded as necessary, inserted in inner wrapper D and sealed by closing the end flap and applying to it the strip of transparent tape carrying the heat-sealing adhesive. The inner wrapper, with the drape sheet enclosed, is then subjected to sterilization in an autoclave, as, for example, for thirty minutes at 250° F. Thereafter, inner wrapper D is removed from the autoclave, inserted in outer wrapper A, and sealed within the latter by applying tape C to flap B. The whole may be shipped, stored and sold in the form illustrated in Figure 1, being opened only when contemplated use of the drape sheet makes it necessary. Thus a sterile drape sheet is available when required for emergency use in circumstances in which sterilizing equipment may be and frequently is lacking.

The drape sheet itself preferably comprises a waterproof body portion of thin, soft, pliable, membranous, somewhat stretchable, more or less transparent, non-porous, non-toxic film. For surgical and like uses, the thickness may vary from about .001" to about .006". Part or all of one side of the film is coated with a very thin, non-toxic, water-resistant or waterproof pressure-sensitive adhesive which adheres tenaciously to the surface of the film. Such adhesive should be able to withstand normal sterilizing tempera-

tures without softening, oozing out or undergoing other substantial changes in its physical properties, in addition to which it should preferably be transparent, normally tacky and water-insoluble, so that no moistening or other treatment will be necessary to bring the adhesive into condition for use. Co-extensive with the body portion or at least with the part thereof which is coated with adhesive is a backing sheet or supporting base which to some extent serves as a liner, particularly when the drape sheet is folded.

In the embodiment of the drape sheet illustrated in detail in Figures 4 to 8, drape sheet F takes the form of a large oblong body portion 1 having therein a transversely extending oval opening 2 surrounded by a small, relatively stiff backing sheet 3, likewise oval in shape, of such dimensions as to overlie body portion 1, overlapping it by about 1½ inches around the edges of opening 2 after the fashion of an elliptical annulus. Between body portion 1 and backing sheet 3 is a pressure-sensitive adhesive, designated 4, which is so formulated in accordance with practices known in the adhesives art that, when employed between body portion 1 and backing sheet 3, it will adhere to both but in the event of intentional separation of the two will have a preferential affinity for body portion 1. Thus it may be applied to body portion 1 before backing sheet 3 is applied to it or, preferably, applied first to backing sheet 3 and then, along with backing sheet 3, applied to body portion 1 in such manner as to form an intervening layer. The opening 2 in body portion 1 and the registering opening in backing sheet 3 may, if desired, be formed before the two are brought into juxtaposition but conveniently may be punched out at one time after the assembly is otherwise complete.

Backing sheet 3, usually of a material that is relatively stiff and often, but not necessarily, thicker than body portion 1, is provided in order to protect adhesive coating 4, which it does by serving as a supporting base or temporary carrier. It enables the film comprising body portion 1 to be handled prior to actual use without likelihood of damage or distortion, particularly in the vicinity of opening 2. As illustrated, backing sheet 3 is formed of a somewhat flexible, preferably waterproof or waterproofed material, which, as distinguished from body portion 1, usually will be non-stretchable.

Ordinarily, but not necessarily in every case, backing sheet 3 will be creped or embossed to provide a plurality of adjacent relatively raised and depressed 130

areas on its inner surface, in which case the raised portions of the inner surface are likely to appear as depressed portions on the outer surface and, to some extent as depressed portions on the opposite or uncoated side of body portion 1. The pattern of these areas will usually be found to have been reproduced by and to be present in adhesive coating 4 after body portion 1 and backing sheet 3 have been separated as hereinafter described. The rough surface formation of backing sheet 3 facilitates separation of the backing sheet from body portion 1; similarly, its reproduction in adhesive coating 4 probably facilitates later separation of body portion 1 from the skin area to which body portion 1 is applied.

Backing sheet 3 may, if desired, be coated or otherwise treated, as with lacquer or by other suitable means, so that it will not be split or delaminated by adhesive coating 4 when it is removed from body portion 1. Backing sheet 3 is, furthermore, less responsive to adhesive coating 4 than is the surface of body portion 1, thus facilitating its removal from body portion 1 by peeling back at an angle. The surface arrangement of backing sheet 3 wherein adjacent raised and depressed areas are formed thereon is effective in bringing about easy removal of backing sheet 3 from adhesive coating 4 even when the adhesive has substantially the same adherent properties per unit of flat surface area relative to backing sheet 3 as it has to body portion 1.

As indicated in Figures 4 to 8, backing sheet 3 has a tab 5 for use in initiating separation of backing sheet 3 and body portion 1. Such tab may be provided by applying the desired adhesive to the inner surface of backing sheet 3, then masking part of the adhesive by means of a strip of smooth-surfaced paper 6 that, when applied, serves to cover the adhesive to an extent sufficient to permit the edge of backing sheet 3 to be manipulated freely, and finally locating backing sheet 3 in the desired position on body portion 1 with adhesive coating 4 between them. Thereafter backing sheet 3 may be grasped by tab 5 and stripped or pulled away from body portion 1, leaving exposed thereon so much of adhesive coating 4 as was not masked off by paper 6. The latter sequence of steps is illustrated in stages in Figures 6 to 8, inclusive.

Body portion 1, with adhesive coating 4 down, is then applied to the skin area of the patient around the wound or incision, if there is one, or to the skin area in which the incision is to be made. If, as in the embodiment of the invention

shown in Figures 4 to 8, body portion 1 is provided in the middle thereof with a symmetrically located opening 2, the latter is centered along or around the wound or incision. Obviously, however, back-sheet 3 and adhesive coating 4 need not necessarily be located around a central opening in body portion 1 but may be located around an opening near one of the ends or may extend linearly along one of the lateral limits thereof, preferably with a tab similar to tab 5 projecting beyond or underlying the edge of body portion 1. In such cases, the drape sheet is so applied to the body of the patient that adhesive coating 4 will be in juxtaposition to the wound or incision and body portion 1 will extend away therefrom in the desired direction.

In the embodiment of the invention illustrated in Figures 9, 10 and 11, drape sheet G takes the form of a film 11 to which a pressure-sensitive adhesive coating 12 has been applied, over most but less than all of one face thereof, as by transfer or off-setting from a supporting base 13. Originally, for example, the adhesive coating may be in contact with supporting base 13 over the greater part of the upper surface of the latter, not including a linearly extending strip at one of its lateral limits. If a similarly shaped film 11 is applied thereto, it will be in contact with the adhesive over all of the lower surface thereof except for a like linearly extending strip, thus leaving an uncoated marginal area 14 by which film 11 may be grasped and manipulated, as in peeling it off supporting base 13. As illustrated in Figures 9, 10 and 11, base 13 takes the form of a diamond-embossed sheet of somewhat stiff supporting paper-like material from which film 11 and adhesive coating 12 may be peeled off simultaneously without leaving any substantial part of adhesive coating 12 on supporting base 13. Once stripped from supporting base 13, film 11 and adhesive coating 12, with the latter down, are applied to the skin area of the patient in the vicinity of the intended incision, which in such case is made directly through body portion 11.

The use of one form or another of our sterile-packaged drape sheet usually eliminates the necessity for using wound towels of the conventional type. If desired, especially with a large drape sheet of the kind illustrated in Figures 4 to 8, excess material may be cut away therefrom after the operation or treatment or, if desired, folded over onto itself to form a bundle which can be made fast over the incision or wound by means of tape strips. By applying a small drape

- sheet, as, for example, a drape sheet of the type shown in Figures 9 to 11, directly over the area of an incision after the operation is completed and the incision closed, dressings may be largely eliminated. Inasmuch as the films comprising the body portions of the drape sheets are preferably more or less transparent; i.e., transparent at least when in immediate contact with the flesh, a surgeon can easily determine, in the first instance, where to make an incision and can watch a wound or incision during healing and make any necessary incisions or punctures for drainage, etc.
- The adjacent skin area is protected from contact with drainage products and thus irritation and possible infection are prevented.
- As previously indicated, the film of which the body portion of our drape sheet is formed is preferably a membranous film that is thin, soft, pliable, and characterized, by virtue of its membranous nature, by an agreeable "handle" or feel. It is desirable that it have good draping properties, particularly if the adhesive coating covers only a minor fractional part of its surface.
- Preferred for purposes of the invention are films that are highly transparent or, if not, at least sufficiently transparent when in immediate contact with the flesh to reveal the texture and color of the skin; however, translucent and even opaque drape sheets may be employed in many cases, if desired.
- The film is preferably, but need not necessarily, be of a somewhat stretchable nature so that it may be conformed to the contour of the body area to which it is attached. Membranous films of the kinds described are usually non-porous and incapable of becoming saturated by perspiration, but in some cases semi-porous films capable of transmitting moisture vapor but not water or like liquids may be utilized to especial advantage. A film thickness or gauge of from about 0.001 to 0.006 inch (but preferably 0.004 inch) is considered best. Films of these characteristics are commercially available from a wide variety of sources.
- Such films may, but need not necessarily be, of the nature of synthetic plastics, by which term as herein used are embraced such materials as synthetic polymers, synthetic elastomers, and plasticized derivatives of cellulose.
- Examples of synthetic polymers are polyvinyl chloride films ("Koroseal" (Registered Trade Mark)), vinylidene chloride polymer films ("Saran" (Registered Trade Mark)), films made from co-polymers of vinyl chloride and vinyl acetate ("Vinylite" (Registered Trade Mark)), and poly-ethylene films ("Polythene"), the latter particularly if modified to preclude softening at unduly low temperatures. Synthetic elastomers include synthetic rubber and rubber-like materials ("Neoprene"), rubber hydrochlorides ("Pliofilm" (Registered Trade Mark)), and the like; however, natural rubber and naturally occurring rubber-like substances are also suitable in many cases. Cellulose derivatives include, along with regenerated cellulose, cellulose esters, cellulose ethers and other derivatives of cellulose; e.g., cellulose acetate, cellulose nitrate, etc.
- The preferred forms of drape sheets employ a "Vinylite" film which is transparent but contains a dye imparting a light greenish tint. It is a calendered film having a thickness of 4 mils (0.004"), formed from a copolymer of vinyl chloride and vinyl acetate, plasticized with about 32% of dioctyl phthalate. The proportion of vinyl acetate relative to vinyl chloride is believed to be in the ratio of about 4:96.
- In lieu of membranous films of the types described, suitable surface-coated textile fabrics may be used in and for the body portion of the drape sheet.
- The backing or supporting element may be treated or untreated fabric, natural or synthetic rubber, a synthetic plastic, or a water-resistant cellulosic material of some suitable type. Among the available types of water-resistant cellulosic materials are parchment, wax-coated paper and moisture-proof Cellophane (Registered Trade Mark). A typical fabric of a kind lending itself to use for these purposes is Holland cloth. If need be, the backing or supporting element is so treated, chemically or otherwise, as to preclude the possibility of splitting or delamination. Whatever the physical and/or chemical nature of the supporting base or backing sheet, its action is principally to protect the adhesive-coated area of the film making up the body portion of the drape sheet; accordingly, its precise nature is not usually important, so long as it serves the intended function, provided it does not break down, come out, or become sticky at sterilization temperatures.
- The pressure-sensitive adhesive, in its preferred form, is a tacky rubber-like copolymer of 2-ethylbutyl acrylate and ethyl acrylate in the weight ratio of 75:25 which is plasticized with triethylene glycol di-2-ethylhexoate (25 parts per 100 of the polymer). Another example is an adhesive composed of a

plasticized methacrylate; for example, isobutyl methacrylate plasticized by the addition of triethylene glycol dibutyl hexoate. The adhesive may, if desired, contain a suitable bactericide. Other than those disclosed above, various types of pressure-sensitive adhesives suitable for the purposes of the invention are known in the adhesives art and may be used in lieu of the preferred types hereinabove described.

A drape sheet so made up may be packaged in any convenient way. For example, instead of being inserted in flat or folded condition in one or more wrappers of the nature of envelopes, as in the case of the wrappers shown in Figures 1 and 2, it may be rolled and inserted in rolled form in a tubular container, in which case it and the container in which it is inserted may be sterilized as a unit and, after sterilization, wrapped, coated with a stripable film ("skin"), or inserted in a tubular container of larger dimensions. If a bactericide is packaged with the drape sheet, with or without sterilization in an autoclave, the outer wrapper, coating or container may in some cases be omitted entirely.

Although we have illustrated particular forms of our sterile-packaged drape sheet and have set out certain procedures and classes of substances which may be used by packaging it, sterilizing it, and constructing it, as, for example, materials available for the film or body portion, for the backing sheet or supporting base, and for the adhesive, it will be understood that many variations and modifications may be made therein without departing from the invention. We therefore do not wish to be limited to the exact materials, arrangements or proportions herein described or the specific surgical uses herein referred to but claim as our invention all embodiments thereof coming within the scope of the appended claims.

What we claim is:—
1. A sterile-packaged drape sheet characterized by comprising: (1) a surgically-sterile adhesive-coated surgical drape sheet formed of a synthetic plastic film sheet which is soft and pliable so as to be readily draped over the contours of the human body, a normally tacky pressure-sensitive adhesive bonded to a rela-

tively small portion of said film so as to provide a skin-adhering area adjacent to a surgical operative site when the drape sheet is applied to a body, the major portion of the drape sheet being adapted to cover a relatively large adjoining skin area without adhering thereto, the film and the adhesive being waterproof and resistant to body fluids and being substantially non-toxic to the human skin; (2) a backing sheet or liner temporarily covering the tacky adhesive area and being removable therefrom without causing offsetting of the adhesive from the film sheet; (3) a sealed package enclosing said drape sheet and adapted to maintain the latter in a surgically-sterile condition, the composite sealed package containing the surgical drape sheet having been sterilized as a unit so as to insure a surgically-sterile condition of the drape sheet therein, said drape sheet being unharmed by said sterilization and being ready for removal and immediate use by a surgeon whenever desired, without further sterilization being required.

2. An article according to claim 1 characterized by the feature that the adhesive strip area surrounds an aperture in the film sheet, the size of the aperture being relatively small compared to the area of the sheet.

3. An article according to claim 1 characterized by the feature that the drape sheet is folded upon itself and is enclosed within an inner wrapper contained in an outer sealed protective envelope.

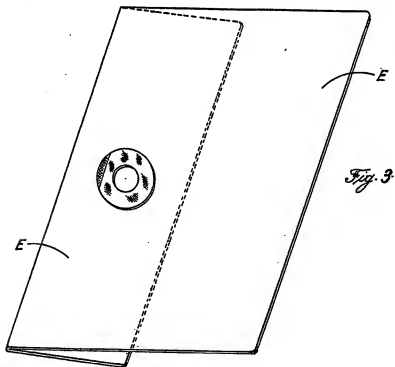
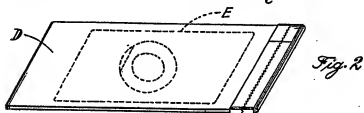
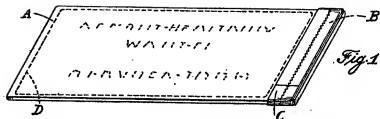
4. An article according to claim 1 characterized by the feature that the drape sheet is transparent or translucent and the film is composed of a synthetic organic polymer.

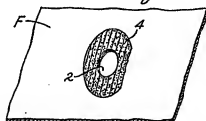
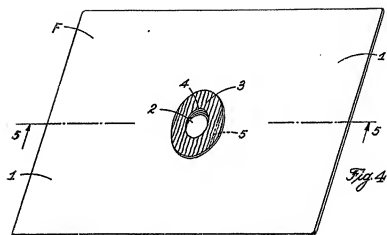
5. An article according to claim 1 characterized by the feature that the pressure-sensitive adhesive is of the acrylate type.

6. An article according to claim 1 characterized by the feature that the pressure-sensitive adhesive includes a bactericide.

7. A sterile-packaged adhesive-coated drape sheet for surgical and like uses substantially as herein described with reference to the embodiments shown in the accompanying drawings.

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692,578 COMPLETE SPECIFICATION

3 SHEETS

This drawing is a reproduction of the Original on a reduced scale.

SHEETS 2 & 3

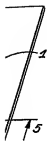


Fig. 4

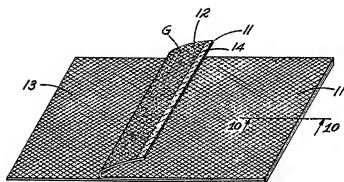


Fig. 9

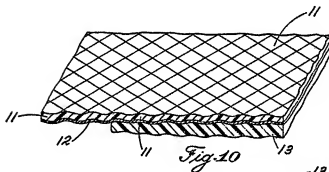


Fig. 10

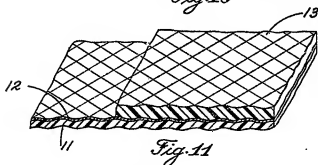


Fig. 11

